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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/037,792 | 03/10/1998 | JOERG ROSENBERG | 04801168 | 7545 |

26474 7590 06/11/2002

KEIL & WEINKAUF
1350 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER

WEBMAN, EDWARD J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1617

DATE MAILED: 06/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/037792

Applicant(s)

ROSENBERG

Examiner

WEBMAN

Group Art Unit

1617

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

☒ Responsive to communication(s) filed on 1/16/02

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 5-11 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 5-11 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☐ All ☐ Some ☒ None of the:

☒ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____.

☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 14

☐ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

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Applicant's election with traverse of Polyvinyl Pyrrolidone (PVP) in Paper No. 18 is acknowledged. The traversal is on the ground(s) that the matrix components relate to a single invention. This is not found persuasive because each polymer recited is substantially different from the other in structure, rendering the claimed matrices different (MPEP 803.2). That is, there is no unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Klimesch et al.

Klimesch et al teach extrudable pharmaceutical compositions (Abstract). Melt extrusion is disclosed (column 2 lines 45-47). PVP is specified (column 2 line 51). Flavorings are disclosed (column 4 line 9). Theophyllines are specified (column 4 line 9). As to the claimed particulate the anticipatory composition must possess such because theophylline melts at 270-274°C whereas Klimesch disclose extrusion temperatures of 50-180°C (column 2 lines 64-65).

Applicants did not respond to the 112 para. I rejection in their response, paper # 13, filed 11/15/00, to the action filed 7/11/90, paper # 12. It is repeated:

Claims 5-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a drug in the second phase or in both phases,

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does not reasonably provide enablement for a drug only in the matrix. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicants do not disclose a second phase such as a particulate that does not contain a drug.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 13 of U.S. Patent No. 6,001,391. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims encompass the instant claims.

No claims allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday to Friday 9 Am 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-0570. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500